REGULATORY GUIDE

NEBRASKA DEPARTMENT OF HEALTH AND HUMAN SERVICES
REGULATION AND LICENSURE

REGULATORY GUIDE 19.0

GUIDE FOR THE PREPARATION OF APPLICATIONS FOR LICENSES FOR NON-SELF-CONTAINED IRRADIATORS

The purpose of this regulatory guide is to provide assistance to applicants and licensees on preparing applications for new licenses, license amendments, and license renewals to possess radioactive material in non-self-contained irradiators, specifically panoramic dry-source-storage irradiators, underwater irradiators, and panoramic wet source-storage irradiators. This type of license is provided for in Title180 Nebraska Administrative Code (NAC) regulations for the “Control of Radiation”, in Chapter 19, "Licenses and Radiation Safety Requirements for Irradiators.” This guide does not cover self-contained dry-source-storage irradiators.

This guide identifies the information needed to complete Agency Form NRH-5, for Application for Radioactive Material License for a non-self-contained irradiator. (Agency Form NRH-5 is shown in Appendix A.) The guide is based on, 180 NAC 19, “Licenses and Radiation Safety Requirements for Irradiators,” and 180 NAC 4, “Standards for Protection Against Radiation,”. Even though the information provided in this guide does not constitute regulatory requirements, applicants should address all the items on Agency Form NRH-5 and should either follow the specific instructions in this guide or provide responses to the items adequate to assure safe operation of the irradiator and compliance with applicable regulations.

Regulatory guides are issued to describe and make available: acceptable methods for implementing specific sections of the Agency's regulations, to delineate techniques used by the staff in evaluating specific problems or postulated problems, or to provide guidance to applicants.

NEBRASKA DEPARTMENT OF HEALTH & HUMAN SERVICES REGULATION AND LICENSURE, REGULATORY GUIDES

Regulatory Guides are issued to describe and make available to the public acceptable methods of implementing specific parts of Title 180 Nebraska regulations, “Control of Radiation”, to delineate techniques used by the staff in evaluating specific problems or postulated accidents, or to provide guidance to applicants, licensees, or registrants. Regulatory Guides are not substitutes for regulations, and compliance with them is not required. Methods and solutions different from those set out in the guides will be acceptable if they provide a basis for the Nebraska Department of Health and Human Services Regulation and Licensure Department, Public Health Assurance Division, Radioactive Materials Program, to make necessary determination to issue or continue a license or certificate of registration.

Comments and suggestions for improvements in these Regulatory Guides are encouraged at all times and they will be revised, as appropriate, to accommodate comments and to reflect new information or experience. Comments should be sent to the Nebraska Department of Health and Human Services, Regulation and Licensure, Public Health Assurance Division, Radioactive Materials Program, 301 Centennial Mall South, P.O. Box 95007, Lincoln, NE 69509.

Requests for single copies of issued guides (which may be reproduced) should be made in writing to the Nebraska Department of Health and Human Services, Regulation and Licensure Department, Public Health Assurance Division Radioactive Materials Program, 301 Centennial Mall South, P.O. Box 95007, Lincoln, NE 68509.

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1. Introduction

After a license is issued, you must conduct its program in accordance with: (1) the statements, representations, and procedures contained in the application and correspondence with the Agency (2) the terms and conditions of the license, and (3) the Agency's regulations. 180 NAC 3, “Licensing of Radioactive Material,” requires that the information provided in the application be complete and accurate in all material respects. Information is considered to be material if it is likely to change or affect an agency decision on issuing the license. The information collections discussed in this Regulatory Guide are covered by Agency Form NRH-5, “Application for Radioactive Material License”.

Applicable Regulations

Agency regulations applicable to irradiator operations are: 180 NAC 10 “Notices, Instructions and Reports to Workers: Inspections”; 180 NAC 4, “Standards for Protection Against Radiation”; 180 NAC 3, “Licensing of Radioactive Material”; 180 NAC 19 “Licenses and Radiation Safety Requirements for Irradiators”; 180 NAC 13, “Transportation of Radioactive Material”; 180 NAC 18, “Fees for Certificates of Registration, Radioactive Material(s) Licenses, Environmental Surveillance, Emergency Response and other Regulatory Services".

2. License Fees

An application fee paid in full is required by 180 NAC 18-004 for all NEW irradiator licenses. (Note that construction of the irradiator may not begin before submitting the license application and fee to the Agency (180 NAC 19-05, 180 NAC 18-005). Refer to 180 NAC 18-005, "Schedule of Fees for Radioactive Materials Licenses" to determine the amount of the fee that must accompany the application. Review of the application will not begin until the full fee has been received. The check or money order should be made payable to the Nebraska Department of Health and Human Services Regulation and Licensure. All application fees may be charged irrespective of the Agency's disposition of the application or the withdrawal of the application.

In addition, to the applicable fee, annual fees will be assessed as described in 180 NAC 18-005.

3. Filing An Application

An application for radioactive material license should be competed on FORM NRH-5 provided by the Agency. Complete items 1 through 5, and 15 on the form. For Items 6 through 14, submit additional information on supplementary pages if needed. Each separate sheet or document submitted with the application should be identified and keyed to the matching item number on the application. You should complete all items in the application in sufficient detail for the Agency staff to determine that your equipment, facilities, training and experience, and radiation safety program are adequate to protect the health and to minimize danger to life and property.

The forms should be completed in duplicate. Retain one copy, because the license will require that you possess and use radioactive material in accordance with the statements and representations in your application and in any supplements to it.

Mail the original application to the Nebraska Department of Health and Human Services Regulation and Licensure.

4. Contents of an Application

This portion of the guide explains, item by item, the information requested on Agency Form NRH-5. Some of the information requested may not be appropriate for all types of irradiators. For example, information on irradiator pools is not relevant to dry-source-storage irradiators, and some information on access control is not relevant to underwater irradiators. If the information requested is not relevant, write “not applicable” for that item. Any applicable sections of the regulations are noted in brackets by the appropriate item. 180 NAC 19-006 allows an applicant requesting use of a teletherapy-type unit for irradiation of materials to propose alternatives for the requirements of 180 NAC 19, and additional information regarding the rationale that must be provided by the licensee is available from the Agency.

The following comments apply to the indicated items on Form NRH-5.

Item 1.a. Applicant's Legal Name and Mailing Address

Individuals should be designated as the applicant only if they are acting in a private capacity and the use of the radioactive materials is not connected with their employment with a corporation or other legal entity. Otherwise, the applicant, should be the corporation or other legal entity applying for the license.

The address specified here should be the mailing address where correspondence should be sent. This may or may not be the same address where the material will be used, as specified in Item 1.b.

Item 1.b. Locations of Use

Specify each location of storage or use by the street address, City, and State or other descriptive address (such as 3 miles west on Highway 81, Anytown, State). A Post Office Box address is not acceptable. Also, specify if a location is one where operations will be conducted at temporary job sites. If a device will be used in a permanent facility or facilities, give the specific address of each if different from 1(a).

Item 2. Department to Use Radioactive Material

Identify the name and phone number of the individual who can answer questions about the application. If this contact changes, please notify the Agency. Notification of a contact change is for information only and would not be considered an application for a license amendment.

Item 3. License Action Type

Self Explanatory

Item 4. Individual User(s)

Specify the person(s) who will directly supervise the use of radioactive material or who will use radioactive material without supervision.

Item 5. Radiation Safety Officer (RSO)

Self-explanatory (See also Item 7 and Item 8)

Item 6. Radioactive Materials Data

For each type of radioactive material to be used, specify:

Item 6.a. The radionuclide to be possessed (e.g., cobalt-60).
Item 6.b. The manufacturer's name and specific model number of each sealed source in the irradiator.

Item 6.b. The number of the certificate of registration issued under 180 NAC 3 by the Agency for each model of sealed source. If a model does not have a certificate of registration, the applicant or the source manufacturer must submit information on the source as required by 180 NAC 3-010 and 180 NAC 3-011.

In general, the use of cesium-137 chloride is not acceptable in pool irradiators or dry-source-storage irradiators that load or unload sources under water at the irradiator because it does not meet the requirements of 180 NAC 19-007.01, Item 3. Cesium-137 chloride is generally acceptable for exclusively dry-use irradiators.

Item 6.c. The maximum amount of radioactive material in any one sealed source, which may be expressed in becquerels or curies. (The use of either becquerels or curies is permitted, but for consistency, only one type should be used throughout the application.)

Item 6.c. The maximum amount of radioactive material to be possessed at any one time, which may be expressed in becquerels or curies, as noted above. The maximum amount should include a margin to allow for source reloading and exchange.

Item 6.d. Purposes for which Radioactive Materials will be Used

Specify the purpose for which the irradiator will be used. An example of an adequate response for a panoramic irradiator is:

Irradiation of products or food.

There will be no irradiation of explosives and no irradiation of more than small quantities of flammable materials with a flash point below 60° (140°F) without specific written authorization from the Agency.

Applicants should note that, in addition to agency approval to operate an irradiator, they must follow the regulations of other Federal agencies that regulate the irradiation of medical products and food.

Prior written authorization from the Agency is required by 180 NAC19-027 before irradiation of more than small quantities of flammable materials with a flash point below 60°C (140°F). As defined in the National Fire Code NFPA 30, “Flammable and Combustible Liquids Code,” published by the National Fire Protection Association,[1] the flash point is “the minimum temperature at which a liquid gives off vapor in sufficient concentration to form an ignitable mixture with air near the surface of the liquid..”According to the NFPA 30 classification system, Class I and Class II liquids have flash points below 60°C (140°F). The flash points of many substances are tabulated in National Fire Code NFPA 325M, “Fire Hazard Properties of Flammable Liquids, Gases, and Volatile Solids.”[2] Flash points are also specified on the Material Safety Data Sheets for

[1]Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, P.O. Box 9146, Quincy, MA 02269-9959 (telephone 1-800-344-3555).

[2]Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, P.O. Box 9146, Quincy, MA 02269-9959 (telephone 1-800-344-3555).

industrial chemicals, when applicable. Examples of common flammable liquids with a flash point below 60°C (140°F) are acetone, benzene, most alcohols, number two fuel oil, gasoline, kerosene, toluene, and turpentine. If the flash point of a flammable liquid is exceeded, the concentration of the vapor in air can exceed the flammable limit and the potential for an explosion can exist. The Agency's concern with irradiating flammable liquids is the possibility of explosion more than the possibility of fire.

The Agency considers that compliance with the requirements in 180 NAC 19-007, 19-010, 19-014, 19-016, 19-017 and 19-019 will provide adequate protection against radiological impacts arising from a fire. The Agency's regulations in 180 NAC 19-010.01 require heat and smoke detectors in the radiation room that, if a fire is detected, will automatically cause the source to become fully shielded and will activate an alarm. Also, 180 NAC 19-010.02 requires a fire extinguishing system; 180 NAC 19-016.09 requires an evaluation of the design of the fire protection and extinguishing systems; 180 NAC 19-017.09 requires tests of the installed detection and extinguishing systems; 180 NAC 19-007.02 requires that the sources be built to withstand a temperature of 600°C (1112°F) for 1 hour followed by the thermal shock of being cooled to 20°C within 15 seconds; 180 NAC 19-014 requires a barrier to protect the source rack; and 180 NAC 19-019.02, item 7 requires an emergency procedure for fires and explosions. With these requirements, the Agency considers that a fire is likely to be controlled without presenting a threat to the integrity of the sources.

With an energetic explosion, however, it is necessary to consider the possibility of direct damage to the source encapsulation or to the source rack such that the rack could not be lowered to the shielded position.

Concerns for preventing an energetic explosion thus can be used to establish a definition for the term “small quantity” of flammable material as used in 180 NAC 19-027.02. A “small quantity” of flammable material can be defined as a quantity of flammable material that, when dispersed evenly throughout the radiation room with no loss to ventilation, would have a concentration below the lower flammable limit concentration. Although local concentrations could exceed the average room concentration, the movement of air into and out of the radiation room provides a margin of safety that is not given credit in the definition of “small quantity.” In addition, no credit is taken for the time required to vaporize all the material, which also adds to the margin of safety. Further, small pockets of flammable vapor will contain quantities of energy too small to provide a driving force sufficient to significantly damage the irradiator. Because of these factors, the definition of small quantity is considered to be sufficiently conservative to ensure safe operation of an irradiator.

An example of determining a small quantity of flammable material is illustrated here. This example considers the irradiation of isopropyl alcohol in a radiation room whose total volume is 100m^3. NFPA 325M states that the lower flammable limit for isopropyl alcohol is 2% by volume, the specific gravity of the liquid is 0.8, and the vapor density relative to that of air is 2.1. The density of air is 1.293 kg/m^3. The volume of isopropyl alcohol in the room at the lower flammable limit will be 2% of 100 m^3, which is equal to 2 m^3. The weight will be 2 m^3 x 1.293 kg/m^3 x 2.1 (density relative to air) = 5.43 kg. With a specific gravity of 0.8, the volume of the liquid isopropyl alcohol would be 6.79 liters. If the liquid mixture were 70% isopropyl alcohol and 30% water, the volume of a small quantity would be 6.79/0.7 = 9.7 liters. Thus, in a radiation room with a volume of 100 m^3, a volume less than 9.7 liters of 70% pure isopropyl alcohol (exposed to the direct radiation beam) can be considered a small quantity because the flammable limit could not be reached over any significant volume even if there were no ventilation.

If the applicant will irradiate small quantities of flammable material, the licensee's records should be sufficient to demonstrate that the above criterion for small quantities has been met, including how the licensee limited the quantity of flammable material in the radiation room at one time.

If the quantity to be exposed to the direct beam at any one time would exceed a small quantity, it is necessary to consider whether the concentration of flammable vapor in the room air could exceed the lower flammable limit. If product movement through the irradiator stopped and the radiation sources could not be returned to the shielded position, the temperature of the irradiated product would rise, the vapor pressure of the flammable material would increase, and that pressure might cause the containers to leak and release flammable vapor into the room air. If ventilation were insufficient, the flammable vapor concentration might exceed the lower flammable limit and a spark could cause the mixture to explode.

In order to obtain Agency approval to irradiate more than small quantities of flammable material, the applicant must demonstrate that it is unlikely that the concentration of flammable vapor in air in a significant volume of the room would exceed the lower flammable limit. There are two methods to do this. The first method is to demonstrate that no single failure would be likely to cause the product to become immobilized in the radiation room and prevent the sources from being returned to the shielded position. Such a situation theoretically might arise if the product carriers became jammed and pushed into the source rack preventing its return to the shielded position. The second method is to demonstrate that even if the product became immobilized and the source rack could not be returned to the shielded position, the ventilation system would be adequate to prevent the concentration of flammable vapor in a significant volume of the room air from reaching the lower flammable limit.

If an applicant is applying for authorization to irradiate more than a small quantity of flammable material, the application should include the name of the flammable material that has a flash point below 60°C (140°F), its flash point, its flammable limit as percent by volume in air, its specific gravity as a liquid, its vapor density relative to that of air, the maximum quantity to be in the direct radiation beam in the radiation room at any one time, and a description of the packaging for the product.

In addition, the application should either (1) describe why a single failure is unlikely to cause immobilization of the product being irradiated with the simultaneous inability to return the sources to the shielded position or (2) describe why the ventilation system will prevent the concentration of vapor in air from exceeding the lower flammable limit in a significant volume of the room if the product is immobilized and the sources cannot be returned to the shielded position. If this second approach is taken, the applicant should also provide a procedure to return the source to the shielded position and remove the product from the radiation room if the ventilation system fails. The procedure should also identify the means to detect ventilation system failure.

Item 7. Training of Individual(s) in Items 4 and 5.

7.1 Radiation Safety Officer (RSO) (180 NAC 3-011.01 and 180 NAC 19-004.04)

Specify the name, training, and experience of the individual who will be responsible for the radiation safety program (the RSO).

An individual may be designated as an alternate RSO. If an alternate RSO is designated, specify the name, training, and experience of that person. If an alternate RSO is designated, describe how any confusion will be avoided about which of these individuals has ultimate responsibility for the radiation protection program. Even if there is an alternate RSO, the designated RSO remains ultimately responsible for the day-to-day operation of the radiation program.

If an RSO is to be replaced, the name, training, and experience of the new RSO should be submitted to the Agency in a license amendment before the new individual assumes the position. If the replacement is sudden, the Agency should be contacted with the information as soon as it is known that the RSO will be changed. While the amendment request is being reviewed by the Agency, the proposed RSO may assume the responsibilities of the RSO position.

Describe the provisions for contacting the RSO in case a problem needing the attention of the RSO arises while he or she is not at the facility or is not in the area.

If the RSO has had neither previous formal training in health physics nor certification by the American Board of Health Physics, the RSO should complete a radiation safety course. Training consisting of approximately 40 hours has typically been considered acceptable by the Agency staff when the training covers the following topics: (1) radioactivity and radioactive decay, (2) interactions of radiation with matter, (3) biological effects of radiation, (4) radiation detection using radiation detection instruments and personnel dosimeters, (5) basic radiation protection principles and good

safety practices (including time, distance, and shielding), and (6) radiation protection regulations. The course should include a written test or evaluation of the individual's comprehension of these topics.

In addition to the above general course, if the RSO has not had prior experience working at an irradiator, he or she should have spent the equivalent of at least 40 hours in self-study or directed study on information directly applicable to radiation safety at irradiators, including applicable regulations (180 NAC 4 and 19) and reports or studies describing safety. Information on irradiator accidents, unusual events, and violations of NRC regulations can be found in the NRC report NUREG-1345, "Review of Events at Large Pool-type Irradiators," E. A. Trager, Jr., March 1989.[3] There should be an evaluation of the individual's comprehension of this information. The license application should list the documents studied or to be studied in the description of the training of the proposed RSO and should describe how the applicant will evaluate the individual's comprehension of the information studied.

The RSO should have at least 3 months (full-time equivalent) of experience at the applicant's irradiator or at another irradiator of a similar type. The 3 months of experience may include preoperational involvement, such as acceptance testing, while the irradiator is being constructed.

7.2 Initial Training for Irradiator Operators (180 NAC 10, 180 NAC 19-004.02 and 180 NAC 19-018)

Describe the training provided to individuals to qualify them to be irradiator operators, including:

1. Classroom training;

2. On-the-job or simulator training;

3. Safety Reviews;

4. Means employed by the applicant to test each individual's understanding of the Agency's regulations and licensing requirements and the irradiator operating and emergency procedures; and

5. Minimum training and experience of personnel who may provide training.

The training required to qualify an individual to be an irradiator operator is described in 180 NAC 19-018. This training should be approximately 40 hours in length for panoramic irradiators and approximately 20 to 30 hours for underwater irradiators. Up to 50% of that time may be self-study or reading time instead of classroom lecture time. The written test described in 180 NAC 19-018.02 should cover the licensee's operating and emergency procedures that the individuals responsible for performing and other operations necessary to safety operate the irradiator without supervision. The on-the-job training described in 180 NAC 19-018.03 should be under the supervision of an experienced operator. If an approved operator does not operate the irradiator for more than a year, his or her performance during operation should (1) be audited for at least a day before he or she is

[3]Copies of NUREG-1345 may be purchased from the Superintendent of Documents, U.S. Government Printing Office, P.O. Box 37082, Washington, DC 20013-7082 (telephone (202)512-2249). Copies are also available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161. A copy is also available for inspection and copying for a fee in the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC.

permitted to operate the irradiator independently and (2) receive a safety review as described in 180 NAC 19-018.04.

The requirements in 180 NAC 19-018.01 thru 19-018.03 are those required for an individual to become qualified initially as an irradiator operator. They do not apply to individuals qualified to be operators before October 30, 1996, the effective date of 180 NAC 19. The safety review and evaluation requirements of 180 NAC 19-018.04 and 19-018.05, however, apply to all operators. Current licensees should conduct a safety review annually.

The subjects, required by 180 NAC 9-018.01, that individuals must be trained in to become an irradiator operator are:

1. The fundamentals of radiation protection as they apply to irradiators. The goal here is to provide the individual with the necessary foundation to perform his or her task safely and to help the individual worker understand the basis for the safety requirements and procedures that will be taught.

2. The requirements of Title 180 NAC 10 and 19 of the Agency regulations. The operator is not expected to be an expert on Agency regulations or to be able to determine whether a given procedure is adequate to meet Agency regulations. Instead, operators should be instructed on the Agency requirements that are directly applicable to their responsibilities.

3. The operation of the irradiator. The objective is to help the person understand the operating and emergency procedures, not to make the individual an engineer.

4. Licensee operating and emergency procedures that the individual will perform. This is the most important part of the training because the safe operation of the irradiator depends on these procedures being followed correctly. The objective is that the operator is able to correctly perform the procedures that he or she will be expected to perform. The training does not have to include procedures that the individual will not perform. For example, if the individual will not perform leak tests, the individual need not be trained in the procedure.

5. Case histories of accidents and problems involving irradiators. The individual should be taught about situations that could lead to trouble. Instruction material on accidents is often difficult to obtain. However, NUREG-1345, “Review of Events at Large Pool-Type Irradiators,” should provide some relevant information. Also, descriptions of events from NRC information notices on irradiators, which are reproduced in Appendix C to this guide, can be used as a source of information. Other sources of information should also be sought.

7.3 Safety Reviews for Operators (180 NAC 9-018.04)

Describe the safety reviews that will be provided to operators to meet the requirements of 180 NAC 19-018.04, including who will conduct these reviews and their training and experience, and how drills will be conducted.

The safety reviews described in 180 NAC 19-018.04 should be about 4 hours per year for panoramic wet-source-storage irradiators and 2 hours per year for dry-source-storage and underwater irradiators. Safety reviews may be conducted once per year or throughout the year on an as-necessary (or an as appropriate basis), as long as the time spent totals 4 hours or more per year. The regulation requires that each operator have a brief written test on the information presented. The word “inspections” in 180 NAC 19-018.04, item 4 means the “evaluations” performed under 180 NAC 19-018.05.

The “drill” in 180 NAC 19-018.04, item 6 means actually going through a procedure using the actual equipment in as realistic a manner as practical, but not necessarily with total realism if that would be

difficult. For example, for a drill on the response to a fire alarm it is not necessary that the alarm actually sound if sounding the alarm would be difficult or disruptive. The operator could be told that the alarm had sounded and asked to do what he would do in that situation. In a drill it is also acceptable to correct errors as they occur rather than waiting until the drill is over. Not all operators must be put through the drill. It is acceptable to have one operator go through the drill and have other operators either watch the drill or be asked to critique or comment on the actions as they occur.

If a senior operator (who might also serve as the RSO, for example) conducts the safety reviews for other operators and prepares the written test for other operators, the preparation of the test and its answers may be considered demonstration that the testing requirement in 180 NAC 19-018.04 has been met by the senior operator.

Item 8. Experience with Radiation of Individuals in Items 4. and 5.

Give specific information on the actual usage experience beyond the training listed in Item 7 of the individual(s) listed.

Item 9. Radiation Detection Instruments

Self Explanatory (See also Item12.5 “Radiation Monitors” and Item 13.2.1 “Operating Procedures” below)

Item 10. Calibration of Instruments Listed in Item 9.

Self Explanatory (See also Item12.5 “Radiation Monitors”, Item 13.2.1 “Operating Procedures” and Item 13.4 “Radiation Detection Instrument Calibrations” below)

Item 11. Personnel Monitoring Devices

Self Explanatory (See also Item13.2.1 “Operating Procedures” below)

Item 12. Facilities and Equipment

12.1 General Description of the Facility and Site (180 NAC 3-010.02, 180 NAC 19-004.05 and 180 NAC 19-016)

Describe the irradiator (in general, not duplicating more detailed information provided in other sections). Include diagrams, sketches, and photographs, as appropriate, to show locations of safety-related equipment and features mentioned in 180 NAC19. In addition, sketch and describe the uses of property adjacent to the facility. Provide a schedule for constructing the irradiator in case the Agency wants to schedule an inspection of the construction.

Special seismic requirements are contained in 180 NAC 19-016.11 for irradiators located in seismic areas. For a license application to operate a panoramic irradiator whose construction will start after October 30, 1996, discuss whether the facility is in a seismic area as defined in 180 NAC 19-002.

Maps of the United States showing seismic areas are published by the U.S. Geological Survey (see S. T. Algermissen et al., "Probabilistic Estimates of Maximum Acceleration and Velocity in Rock in the Contiguous United States."[4])

12.2 Access Control (180 NAC 19-004.05, 180 NAC 19-008, 180 NAC 19-012.01, 180 NAC 19-016.08, 180 NAC 19-017.07)

12.2.1 Describe the access control system and how it works with respect to the requirements of 180 NAC 19-008. Include drawings or sketches as appropriate. For panoramic irradiators, describe the alarm systems and who will be made aware of alarms. Describe the lock and key system for controlling source movement and discuss how it meets the requirements of 180 NAC 19-012.01.

It is important for the description to be in enough detail to allow the agency license reviewer to determine that the design of the access control system is adequate to meet all the requirements of 180 NAC 19-008. An acceptable way to do this is to quote the section, sentence-by-sentence or paragraph-by-paragraph, and provide the relevant description underneath.

12.2.2 Training for Other Individuals Permitted Unescorted Access to Restricted Areas (180 NAC 10-003)

According to 180 NAC 10-003, all individuals likely to receive an occupational dose must receive appropriate instruction on radiation safety. Describe the training to be provided to meet this requirement.

Discussion

The requirement in 180 NAC 19-008 for a door or other physical barrier applies to each entrance of the radiation room of a panoramic irradiator, whether intended for personnel access or intended solely for product entrance or exit. Panoramic irradiators with a conveyor system could meet the requirement by providing such small clearances around the product carriers that a person could not squeeze through or by using barriers that would require unusual exertion to bypass. A photoelectric system cannot be considered a physical barrier. The requirement is that the door or barrier must prevent inadvertent entry by a person, not that it need prevent a deliberate or determined effort to bypass the barrier. The purpose of this requirement is to prevent someone from carelessly, inattentively, or accidentally entering the radiation room while the source is exposed.

This section also requires an independent backup access control system on panoramic irradiators. The purpose of the backup system is to provide a redundant means of preventing a person from being accidentally exposed to the source. In case of a failure of the interlocks on the door or barrier combined with a failure to follow operating procedures, the backup system should warn the person entering the radiation room of the danger and automatically cause the sources to return to their shielded position. The backup system could use photoelectric cells in an entrance maze, pressure mats on the floor, or similar

[4]United States Department of the Interior, Geological Survey, Open-File Report 82-1033, 1982. This report may be purchased for S24.50 from: U.S. Geological Survey, Books and Report Sales, Box 25425, Denver, Colorado 80224. Prepayment is required. Minor updates of this report are possible as new information becomes available.

means to detect a person entering the radiation room while the source is exposed. The system must also alert another person of the entry. That person must be prepared to render or summon assistance.

12.3 Shielding (180 NAC 19-009, 180 NAC 19-016.01, 180 NAC 19-016.10, and 180 NAC 19-017.01) For panoramic irradiators, describe the shielding to be used and its composition. A diagram should show the configuration of shielding walls and indicate the thickness of each. Penetrations in the shield wall should be indicated. If any accessible areas outside the shield are expected to have a dose rate exceeding 0.02 millisievert (2 millirems) per hour, identify the areas and tell how access to those areas will be controlled. Explain how compliance with the 100 mrem/year dose limit for the public in 180 NAC 4-013.01, item 1 will be achieved. For panoramic irradiators whose construction will start after October 30, 1996, identify building code requirements to which shielding walls will be built and inspections of the construction that will be performed by local authorities. For requests to possess more than 2 x 10^{17} becquerels (5,000,000 curies) in a panoramic irradiator, describe how cooling of the shielding walls will be accomplished (180 NAC 19-016.01). If the irradiator is an underwater irradiator, state "Not applicable" for this section.

Discussion

The intent of 180 NAC 19 is that shield walls retain their integrity in the event of an earthquake by requiring that they be designed to meet the seismic requirements of local building codes or other appropriate sources. For irradiators whose construction starts after October 30, 1996, and that are not located in seismic areas, as defined in 180 NAC19-002, it is acceptable that shielding meet generally accepted building code requirements for reinforced concrete, for example, American Concrete Institute Standard ACI 318-89, "Building Code Requirements for Reinforced Concrete."[5]

In seismic areas, local building codes are likely to specify requirements for such things as spacing of reinforcing bars, how to tie reinforcing bars together, preferred arrangements for reinforcing bars, and requirements for joining reinforcing bars to floor slabs. If local building codes do not contain seismic requirements, "other appropriate sources" could include Chapter 21, "Special Provisions for Seismic Design," of the American Concrete Institute Standard ACI 318-89, "Building Code Requirements for Reinforced Concrete."

12.4 Fire Protection (180 NAC 19-010 and 180 NAC 19-017.08)

For panoramic irradiators, describe the type and location of the heat and smoke detectors to be used to detect a fire in the radiation room. Use diagrams and sketches, as appropriate. (The heat and smoke detectors should be able to promptly detect a fire, but they do not necessarily have to be located within the radiation room.) Describe the alarms to alert personnel capable of summoning assistance. Describe how the sources will automatically become fully shielded if fire is detected. Describe how the heat and smoke detectors will be tested.

If the irradiator is an underwater irradiator, write "Not applicable" because 180 NAC 19-010 contains no fire protection requirements for underwater irradiators, since the sources are always underwater and not subject to damage by fire.

[5]This standard is available for purchase from the American Concrete Institute, Box 19150, Redford Station, Detroit, Michigan 48219.

For panoramic irradiators, describe the fire extinguishing system that is capable of extinguishing the fire without personnel entering the room. Describe how flooding into unrestricted areas will be avoided. Identify the location of shut-off valves. If the fire detection or extinguishing systems are built to meet fire protection codes, those codes should be identified. Describe the acceptance testing of the systems.
Irradiator applicants who wish to apply for an exemption from the requirement for a fire suppression system should provide the following information:

1. The maximum quantity of combustible materials that may be in the room;

2. The procedures used to ensure that the maximum quantity of combustible materials will not be exceeded;

3. The reasons a fire will not prevent the sources from returning to the shielded position; and

4. Evidence of approval by local fire officials.

This exemption is likely to be more appropriate for research facilities, rather than large commercial irradiation facilities that may have large volumes of cardboard boxes as well as other combustible materials.

12.5 Radiation Monitors (180 NAC 19-008.03, 180 NAC 19-011, 180 NAC 19-016.06, 180 NAC 19-017.05 and 180 NAC 19-022.02)

Describe the location and type of monitors used to meet the requirements of 180 NAC 19-008.03, 180 NAC 19-011 and 180 NAC 19-022.02. Describe the location and types of alarms and who will be alerted by the alarms. Use diagrams and sketches, as appropriate. Discuss the alarm set-points or the methods for establishing the alarm set-points. In general, G-M detectors are considered to have adequate sensitivity. For irradiators whose construction begins after October 30, 1996, describe the evaluation performed to meet 180 NAC 1-019.16.06 on detector location and sensitivity and the acceptance testing that will be performed to meet 180 NAC 19-017.05.

12.6 Irradiator Pools (180 NAC 19-013, 180 NAC 19-016.03 and 180 NAC 19-017.03)

Describe the pool lining. For irradiators without a stainless steel liner that were initially licensed after October 30, 1996, explain why the pool has a low likelihood of substantial leakage and how decontamination could be accomplished if necessary. For irradiators first licensed prior to October 30, 1996, write “Not applicable.”

Describe the high and low water-level indicators and their locations. Describe the purification system for the pool; explain why the purification system is considered capable of maintaining pool water conductivity less than 20 microsiemens per centimeter. Describe the means to replenish pool water. Describe the barrier used during normal operation to prevent personnel from falling into the pool. Describe how high radiation doses from radiation streaming will be avoided when using long-handled tools or poles. Use sketches if appropriate.

For irradiators first licensed after October 30, 1996, if the pool has outlets more than 0.5 meters below the surface that could allow water to drain out of the pool, describe the means of preventing inadvertent excessive loss of pool water. (Outlets in this context do not include transfer tubes between adjacent pools because the transfer tubes do not provide a means to allow water to drain out of the pools.)

For irradiators whose construction started after October 30, 1996, describe how the pool design ensures its integrity as required by 180 NAC 19-016.03, how the design of the water purification

system is adequate, and how the inspections and tests to be done meet the requirements of 180 NAC 19-017.03 and 180 NAC 19-017.04.

12.7 Source Rack Protection (180 NAC 19-014)

If the product moves on a product conveyer system, describe the source rack protection to be provided to prevent products and product carriers from hitting or touching the source rack or mechanism that moves the rack. Provide diagrams or sketches if appropriate.

12.8 Power Failures (180 NAC 19-015, 180 NAC 19-016.10, and 180 NAC 19-017.09)

For panoramic irradiators, describe how the source rack will be lowered if offsite power is lost for longer than 10 seconds. Describe how loss of power will affect the lock on the doors in the radiation room for a panoramic irradiator. For irradiators whose construction begins after October 30, 1996, to meet 180 NAC 19-016.10, describe the automatic return of the source rack to the fully shielded position in the event of a power failure, and describe the testing of that function to meet 180 NAC 19-017.09.

Item 13. Radiation Protection Program

13.1 Organizational Structure and Authorities and Responsibilities of Management (180 NAC 19-004.04)

Describe the organizational structure for managing the irradiator, specifically the radiation safety responsibilities and authorities of the RSO and those other management personnel who have important radiation safety responsibilities and authorities. In particular, the application should describe who has the authority to stop unsafe operations. Appendix B provides a list of the RSO's responsibilities that is acceptable to the Agency staff; applicants may incorporate this list in their applications.

The RSO should have independent authority to stop operations that he or she considers unsafe and to conduct tests or measurements considered to be necessary. The RSO should be relatively independent of production responsibilities, to the extent practical, considering the size of the staff at the irradiator. The RSO should report directly to the irradiator manager. The RSO should have sufficient time and commitment from management to fulfill the responsibilities listed in Appendix B.

13.2 Operating and Emergency Procedures (180 NAC 19-004 and 180 NAC 19-019)

An applicant may submit an outline or summary of its written operating and emergency procedures. This outline should allow licensees the flexibility to change procedures in ways that do not affect safety without the need for a license amendment.

The outlines or summaries of the written operating and emergency procedures should have enough detail to allow the Agency license reviewer to determine that following the steps outlined will ensure compliance with the Agency regulations.

13.2.1 Operating Procedures

As described in 180 NAC 19-019, operating procedures are required for the following topics:

1. Operation of the irradiator, including entering and leaving the radiation room. The description should be in enough detail to show how compliance with 180 NAC 19-026, “Entering and Leaving the Radiation Room,” will be achieved and should include a description of the initial entry and survey after an irradiation. Describe how access to keys by individuals who have not been qualified to be operators will be prevented, as required by 180 NAC 19-012.01. At a panoramic irradiator when product movement is occurring, 180 NAC 19-025 requires the presence of an irradiator operator and another person who is trained on how to respond and prepared to render or summon assistance if the access alarm sounds. For static irradiations, a person who is trained to respond to alarms must be onsite. In 180 NAC 19-025, the term “onsite” is intended to give flexibility to licensees. For example, for a research irradiator at a university, the onsite person could be a guard located on campus but not in the building containing the irradiator provided the guard would hear the alarm and was trained as required by 180 NAC 19-018.07. The guard would not have to be trained as an irradiator operator.

2. Use of personnel dosimeters. The description should include the categories of personnel who must wear dosimeters; the locations in the facility they must be worn; and how the requirements of 180 NAC 19-020, "Personnel Monitoring," will be met. The use of personnel dosimeters should begin before opening shipping casks containing sources.

3. Surveying the shielding of panoramic irradiators. The description should include how the surveys required by 180 NAC 19-021.01 will be done, including the types of instruments to be used. The initial survey should be considerably more thorough than subsequent surveys and should be performed by a well-qualified individual, such as the radiation safety officer or a health physics consultant. The initial survey should emphasize accessible areas, especially frequently occupied areas, areas around penetrations, and entrances to the radiation room, but should also include some locations not easily accessible. If the measured radiation dose rates are not distinguishable from normal background, the survey may indicate “background,” rather than a numerical value. (Because of statistical fluctuations in the dose rate, the survey meter readings will fluctuate. Establish a range of dose rates to represent the natural background radiation dose rate. Readings within the range may be entered as background on survey records.) Describe the actions to be taken if radiation levels exceed the limits specified in 180 NAC 19-009.

4. Monitoring pool water for contamination before the pool water is released to unrestricted areas. The description should include the types of instruments to be used, their estimated sensitivities, methods and frequency of calibration, and how the requirements of 180 NAC 19-022.02 will be met. In addition, this procedure or another procedure should describe the surveys of other potentially contaminated liquids, sediments from pool vacuuming, and resins whose monitoring is required by 180 NAC 19-021.04 or 19-021.05. In general, the sensitivity required can be obtained with a thin-window G-M probe; sodium iodide detectors are generally not necessary. If water from the irradiator pool or resins is monitored in a low background area (less than 0.5 microsievert or 0.05 millirem per hour) and no radiation above background is measured, the material may be considered nonradioactive and released without restriction. For this item, write “Not applicable” for dry-source-storage irradiators.

5. Leak testing of sources. If the applicant will perform its own leak testing for dry-source-storage irradiators, describe the leak testing procedure, including (1) the instruments to be used and their calibration method and frequency, (2) the methods of performing the analyses, and (3) the pertinent training of the individual who analyzes the samples. Describe how the sample will be collected and analyzed. The wipe should be taken on the accessible surface closest to the source, not wiping the source itself. The value of 200 becquerels (0.005 microcurie) applies to each source individually and

is an action level that means that the contamination should be investigated, not that there necessarily is a leaking source. In general, the sensitivity required can be obtained with a thin-window G-M probe; sodium iodide detectors are generally not necessary.

If the licensee will not perform the leak testing, identify who will perform the leak test and either provide their license number or provide the procedures they will use.

This procedure applies to dry-source-storage irradiators only; for pool irradiators write "Not applicable."

6. Inspection and maintenance checks required by 180 NAC 19-023. Do not describe the inspection and maintenance procedures here. Instead, describe these procedures under Item 13.3 below.

7. Loading, unloading and repositioning sources (if the operations will be performed by the licensee). All radiation safety aspects should be described, including contamination surveys of the shipping cask, radiation monitoring during operations, and recording the location of each individual source placed in the source rack. If the loading, unloading, or repositioning will not be performed by the licensee, identify who will perform these services.

8. Inspection of movable shielding required by 180 NAC 19-008.08, if applicable.

13.2.2 Emergency or Abnormal Event Procedures

The emergency and abnormal event procedures listed below should include who will be notified of the event, whether the Agency will be notified, the role of the RSO, and what records of the event will be kept. The procedures should include the initial actions to be taken immediately after discovering the emergency or abnormal event. The procedures generally should not include postemergency corrective actions and repairs, since there will be time to carefully consider such actions on a case-by-case basis after the situation is under control. Describe procedures for each of the following:

1. Sources stuck in the unshielded position.
2. Personnel overexposures.
3. A radiation alarm from the product exit portal monitor or pool monitor.
4. Detection of leaking sources, pool contamination, or an alarm caused by contamination of pool water. The description should include who will be notified and how the requirements of 180 NAC 19-022.03 will be met.
5. A low or high water-level indication, an abnormal water loss, or leakage from the source storage pool. (The procedure should address all three of these conditions, but should generally include only the initial emergency response, not subsequent actions or postemergency repairs.)
6. A prolonged loss of electrical power (more than 10 seconds). Be sure to include entry procedures.
7. A fire alarm or explosion in the radiation room.
8. An alarm indicating unauthorized entry into the radiation room, area around the pool, or another alarmed area.
9. Natural phenomena, including an earthquake, a tornado, flooding, or other phenomena as appropriate for the geographical location of the facility.
10. Jamming of the automatic conveyor systems.

13.2.3 Training for Individuals Other than Authorized Users Who Must Respond to Alarms (180 NAC 10-003 and 180 NAC 19-018.07)

Describe the training and testing to be given to employees other than irradiator operators who must be prepared to respond to alarms as described in 180 NAC 19-018.07. Describe the annual refresher training. Identify who (by category of worker) will be given the training. If the individuals who will respond to alarms are not facility employees (for example, a local fire department), describe any training or orientation that will be offered. (Testing of non-employees is not expected.)

The training and testing should be sufficient to determine that the person knows what to do in case of an alarm. The preferred type of testing is a drill in which the person being tested responds to an alarm while being observed by an evaluator. Drills should be repeated until the evaluator is satisfied with the response. After initial training, there should be annual refresher training and testing.

13.3 Inspection and Maintenance (180 NAC 19-004.08, 180 NAC 19-019.01, item 6, and 180 NAC 19-023)

Describe the inspection and maintenance checks required by 180 NAC 19-023, including the frequency of the checks. The required checks are:

1. Operability of each aspect of the access control system required by 180 NAC 19-008.
2. Functioning of the source position indicator as required by 180 NAC 19-012.02.
3. Operability of the radiation monitor for radioactive contamination in pool water required by 180 NAC 19-022.02, using a radiation check source, if applicable.
4. Operability of the over-pool radiation monitor at underwater irradiators as required by 180 NAC 19-011.02.
5. Operability of the product exit monitor required by 180 NAC 19-011.01.
6. Operability of the emergency source return control required by 180 NAC 19-012.03.
7. Leak-tightness of systems through which pool water circulates (visual inspection).
8. Operability of the heat and smoke detectors and extinguisher system required by 180 NAC 19-010 turning extinguishers on.
9. Operability of the means of pool water replenishment required by 180 NAC 19-013.03.
10. Operability of the indicators of high and low pool-water levels required by 180 NAC 19-013.04.
11. Operability of the intrusion alarm required by 180 NAC 19-008.09, if applicable.
12. Functioning and wear of the system, mechanisms, and cables used to raise and lower sources.
13. Condition of the barrier to prevent products from hitting the sources or source mechanics as required by 180 NAC 19-014.
14. Amount of water added to the pool to determine whether the pool is leaking.
15. Electrical wiring on required safety systems for radiation damage.
16. Pool water conductivity measurements as required by 180 NAC 19-024.

13.4 Radiation Detection Instrument Calibrations (180 NAC 19-020.02, and 180 NAC 19-021.03)

Specify how survey instruments and pocket dosimeters (if used) will be calibrated or provide the name, address, and the Agency license number of the organization that will provide the service (and that is licensed to perform this activity.)

Discussion

It may be that a calibration service company does not have a license, perhaps because it is located in a non-Agreement State and uses radium, a radioactive material not regulated by the NRC. It is also possible that a service company has a license, but the license does not specifically authorize it to provide instrument calibration services to other licensees. In these

cases, submit a description of the radioactive sources and the procedures used by the company for calibrating survey instruments.

Applicants who plan to calibrate their own radiation survey instruments should describe the radiation source to be used (radionuclide, activity, manufacturer, and model number) and the written procedures for calibrating the survey instruments. The training and experience of the individual who will calibrate the instruments should also be described. As a minimum, the written procedures should specify that:

1. Calibration will be performed at least annually with radionuclide sources at distances sufficient to approximate point sources.
2. Survey instruments will be calibrated at two points on each scale or range that the instrument offers or one point per decade for digital instruments, up to 0.01 sievert (1 rem) per hour. (Calibration is likely to require at least the following activities of typical radionuclide sources: 3000 gigabecquerels (80 millicuries) of cesium-137, 700 gigabecquerels (20 millicuries) of cobalt-60, or 1000 gigabecquerels (30 millicuries) of radium-226.)
3. Survey instruments will be adjusted to provide readings on all calibrated scales or ranges within 20% of true value.

If pocket dosimeters are to be used, describe the response checks to be performed and the range of the dosimeters. An annual response check with a response within +30% of the true dose is acceptable. High-range pocket dosimeters are not required since the purpose of these dosimeters is essentially to demonstrate that little or no dose was received.

13.5 Pool Water Purity (180 NAC 19-013.05, 180 NAC 19-016.04, 180 NAC 19-017.04 and 180 NAC 19-024]

Describe the equipment to maintain pool water purity and clarity, the frequency of measurements of purity, and the criterion to be used for acceptable purity (e.g., 20 microsiemens per centimeter or equivalent). If conductivity meters are to be used, describe the method and frequency of calibration.

Describe what actions will be taken to lower pool water conductivity if the conductivity rises above 20 microsiemens per centimeter.

For dry-source-storage irradiators, write “Not applicable”.

Discussion

The purpose of keeping the water clean is not only to keep the water clear, but also to reduce corrosion of the sources. Clear water is desirable so that the sources and source rack can be visually inspected to check their condition and to retrieve any items that may drop into the pool. The probability of corrosion can be reduced by controlling impurity levels. The requirements in 180 NAC 19-024 are written in terms of conductivity (20 microsiemens per centimeter) because conductivity, an indicator of impurity levels, is most easily measured and most commonly used as a measure of water purity. Chlorides are one of the most aggressive impurities in promoting corrosion of stainless steel, and chloride concentrations should be controlled to 3 parts per million or less. Water with a conductivity of less than 20 microsiemens per centimeter will normally have a chloride concentration of less than 3 parts per million. However, in some situations high water conductivities may be caused by impurities other than chlorides. In such situations, if it can be shown that those impurities at the concentrations present do not promote corrosion, it may be more appropriate to base purity control on measurements of chloride concentrations rather than conductivity so that a conductivity much higher than 20 microsiemens per centimeter could be permitted. If the applicant elects to control impurities on the basis of chloride concentrations, the applicant should apply for an exemption to 180 NAC 19-024.

Requests for exemptions that commit to maintaining chloride concentrations to less than 3 parts per million are likely to be granted.

13.6 Loading and Unloading Sources (180 NAC 19-004.07)

If the applicant's own personnel will load and unload sources, describe the qualifications and training of the personnel and the procedures to be used. If the applicant will contract for source loading and unloading, identify the organizations that will be used.

13.7 Review of the Radiation Protection Program (180 NAC 4-005.03)

Describe the review of the content and implementation of the radiation protection program that is described in this Item 10. Describe how the review will be conducted and who (by position) will conduct the reviews. Describe who will review the results of the review and any recommendations made in the review.

Discussion

The review should include (1) a review of the adequacy of the operating and emergency procedures listed in 180 NAC 19-019, (2) a review of the results of the inspection and maintenance checks listed in 180 NAC 19-023, (3) a review of personnel monitoring results, (4) a review of radiation survey and monitoring results, and (5) a review of the adequacy of the training of workers. Ideally, the person who conducts the review should be knowledgeable in radiation protection but independent of the day-to-day operation of the radiation protection program.

13.8 Financial Assurance and Recordkeeping for Decommissioning (180 NAC 3-018)

Irradiator applicants are required by 180 NAC 3-018.02 to submit either (1) a certification that financial assurance for decommissioning has been provided in the amount of $75,000 or (2) a decommissioning funding plan that contains a cost estimate for decommissioning (generally to justify a cost of less than $75,000) plus a certification that financial assurance for decommissioning has been provided in an amount equal to the cost estimate. For information on financial assurance mechanisms, the applicant should consult NRC's Regulatory Guide 3.66, "Standard Format and Content of Financial Assurance Mechanisms Required for Decommissioning Under 10 CFR Parts 30, 40, 70, and 72."

For license renewal applications in which the applicant has previously provided financial assurance of $75,000, write "Certification for financial assurance was submitted previously." For license renewal applications in which the applicant previously submitted a decommissioning funding plan with a cost estimate less than $75,000, the cost estimate should be updated and financial assurance should be provided for the new cost amount.

Applicants should list the records that will be maintained to company with 180 NAC 3-018.07 and should specify the location where the records will be kept. No records are required by 180 NAC 3-018.07, item 1 and 2 if no spills or contamination have occurred. Records are required for 180 NAC 3-018.07, item 3 only if a decommissioning funding plan to justify an amount other than $75,000 was submitted.

Item 14 Waste Management

The general requirements for disposal of licensed radioactive material are contained in 180 NAC 4-039.01 through 4-045. Because of the nature of the licensed material contained in irradiators, the only option for

disposal is to transfer the material to an authorized recipient as specified in 180 NAC 4-039.01, item 1. This states, in part, that sealed sources will be shipped only to authorized recipients and transport must be in accordance with 180 NAC 13. The transfer should be done as soon as practical after there is no further use for the sources.

Authorized recipients are the original supplier of the irradiator sealed sources, a commercial firm licensed by the Agency to accept radioactive waste from other persons, and another specific licensee authorized to possess the licensed material. No one else is authorized to dispose of licensed material.

Item 15 Certification

An application should be dated and signed by a representative of the corporation or legal entity who is authorized to sign official documents and to certify that it contains information that is true and correct to the best of his or her knowledge and belief. Unsigned applications will be returned for proper signature.

Correspondence to the Agency from the applicant should be signed by the certifying official named in Item 15. The Agency will send correspondence to that official. Commitments made by the applicant must be signed by the official listed in Item 15.

5. AMENDMENTS TO A LICENSE

After you are issued a license, you must conduct your program in accordance with (1) the statements, representations, and procedures contained in your application, (2) the terms and conditions of license, and (3) Title180 NAC.

It is your obligation to keep your license current. You should anticipate the need for a license amendment insofar as possible. If any other information provided in your application is to be modified or change submit an application for a license amendment. In the meantime, you must comply with the terms and conditions of your license until it is actually amended; Title 180 do not allow you to implement changes on the basis of a submission requesting an amendment to your license.

An application for a license amendment may be prepared either on the application Form NRH-5 or in letter form and should be submitted to the address specified in Section 3 of this guide. Your application should identify your license by number and should clearly describe the exact nature of the changes, additions, or deletions. References to previously submitted information and documents should be clear and specific and should identify the pertinent information by date, page, and paragraph. For example, if you wish to change the "responsible individual" specified in Item 5, your application for license amendment should specify the new responsible individual's name, training and experience. The qualifications of the new responsible individual should be equivalent to those specified in Item 5 of this guide.

6. RENEWAL OF A LICENSE

Licenses are issued for a period of up to 5 years. You must send an application for renewal to the address specified in Section 3 of this guide. You may be required to submit an entirely new application for renewal as if it were an application for a new license without referring to previously submitted information. (This approach is preferable for the first renewal after October 30, 1996, the effective date of Section 019.)

As an alternative, applicants may:

1. Review the current license to determine whether the information concerning the sealed sources and the irradiator accurately represents the current and anticipated program. Identify any additions, deletions, or other changes and then prepare information appropriate for the required additions or changes.

2. Review the documents submitted in the past to determine whether the information in them is up to date and accurately represents the facilities, equipment, personnel, radiation safety procedures, locations of use, and so on. The documents that represent the current program should be identified by date. Any out-of-date or superseded documents should also be identified. Identify any changes that should be made in the documents to reflect the current program.

3. Review Title 180 to ensure that any changes in the regulations are appropriately covered in the program description.

4. After this review is completed, submit a letter to the Agency in duplicate, with the proper fee, requesting renewal of the license and providing the information specified in Items 1, 2, and 3, as necessary.

5. Include the name and telephone number of the person to be contacted about the renewal application and include the current mailing address if it is not indicated correctly on the license.

   Discussion

   If an application for license renewal is filed at least 30 days before the expiration date of the license and the appropriate fee for license renewal is included, 180 NAC 3-019 provides for the license to remain in effect until the Agency takes final action on the application. However, if an application is filed less than 30 days before the expiration date and the Agency cannot process it before that date, the license will expire.

   It is important that the appropriate fee accompany the application for license renewal and that the application is dated and signed by a representative of the corporation or legal entity who is authorized to sign official documents and certify that it contains information that is true and correct to the best of his or her knowledge or belief. In accordance with 180 NAC 18 the Agency will not accept an application for filing or processing before the proper fee is paid. Unsigned applications will be returned for proper signature.

7. TERMINATION OF A LICENSE

To terminate a license, 180 NAC 3-019 requires that a licensee notify the Agency. A termination report must be sent to the Agency before the expiration date of the license. If there is loose contamination at the irradiator, it will also be necessary to submit a decommissioning plan as described in 180 NAC 3-019.

If all the licensed radioactive material cannot be disposed of properly before the expiration date, a request for license renewal for storage only of the radioactive material must be provided to the Agency. The renewal is necessary to avoid violating the Agency's regulations that do not allow possession of licensable material without a valid license.

NEBRASKA DEPARTMENT OF HEALTH AND HUMAN SERVICES REGULATION AND LICENSURE
DIVISION OF PUBLIC HEALTH ASSURANCE
RADIOACTIVE MATERIALS PROGRAM

APPLICATION FOR RADIOACTIVE MATERIAL LICENSE

INSTRUCTIONS - (Use additional sheets where necessary.)
New or Renewal Application - Complete Items 1. through 15.
Amendment to License - Complete Items1.a, 3., and 15. And indicate other changes as appropriate.
Retain one copy for your files and submit original application to: Department of Health and Human Services Regulation and Licensure, Division of Public Health Assurance, 301 Centennial Mall South, P.O. Box 95007, Lincoln, NE 68509-5007.
Upon approval of this application, the applicant will receive a Radioactive Material License, issued in accordance with the requirements contained in Nebraska Regulations for the Control of Radiation and the Nebraska Radiation Control Act.

1.a Legal Name and Street address of Applicant (Institution, Firm, Person, etc.)

Applicant Name: _____

Address: _____

_____

City, State Zip +4: _____

Telephone #: _____

FAX #: _____

eMail Address:

1.b Street address(es) at which Radioactive Material will be used. (If different than 1.a)

(1) Permanent Address: _____

_____

City, State Zip+4: _____

(2) Temporary Job Sites Throughout Nebraska? ❒ Yes ❒ No

2. Department to Use Radioactive Material

_____

Person to Contact:_____

Telephone #:_____

3. This is an application for:

❒ New License

❒ Amendment to License No._____

❒ Renewal of License No._____

4. Individual User(s)

❒ Individual users approved by the Licensee's radiation safety committee.

❒ Individual users approved by the Licensee's radiation safety officer.

❒ Individual users satisfy the requirements of 180 NAC 3-013

OR

❒ Name and Title of individual(s) who will use or directly supervise use of, Radioactive Materials. Give training and experience in Items 7. And 8.

First Name + Middle Initial | Last Name | Title

5. Radiation Safety Officer (RSO)
(Name and Title of Individual designated as Radiation Safety Officer.

_____

Telephone #:_____

Attach documentation of his/her training and experience as in Items 7. and 8.

Agency Use Only

Date Received Stamp

6. Radioactive Material Data

❒ Type B Broad Scope, 180 NAC 3-013.01, item 2

❒ Type C Broad Scope, 180 NAC 3-013.01, item 3

❒ Specific License, Radioactive Material Listed below:

6.a. Element and Mass Number	6.b. Chemical or Physical Form (Make and Model if sealed source)	6.c. Maximum Activity Requested (Expressed as Curies, Millicuries or Microcuries)	6.d. Use of Each Form (If sealed source, also give Make and Model Number of the storage and/or device in which sealed source will be stored and/or used)

7. Training of Individuals in Items 4. and 5.

Name of Individual:

	Formal Course Title	Location and Date(s) of Training	Clock Hours in Lecture or Laboratory
7.a. Radiation Physics and Instrumentation			
7.b. Radiation Protection			
7.c. Mathematics Pertaining to the Use and Measurement of Radioactivity			
7.d. Biological Effects of Radiation			

8. Experience with Radiation of Individuals in Items 4. and 5.

(Actual use of Radioisotopes or Equivalent Experience)

Name of Individual:

Isotope	Maximum Activity	Where Experience Was Gained	Months/Years	Type of Use

9. Radiation Detection Instruments

Type of Instrument	Manufacturer's Name	Model Number	Number Available	Radiation Detected	Sensitivity Range

10. Calibration of Instruments Listed in Item 9.

❒ **a. Calibrated by Service Company**	❒ **b. Calibrated by Applicant**
Name and Address of Service Company and Frequency of Calibration	

11. Personnel Monitoring Devices

(Check and/or complete as appropriate)

Type	Supplier (Service Company)	Exchange Frequency
❒ Film Badge ❒ TLD ❒ DOSL ❒ Other (Specify): _____		❒ Monthly ❒ Quarterly ❒ Other (Specify): _____

Information to be Submitted on Additional Sheets

12. Facilities and Equipment

Describe laboratory facilities and remote handling equipment, storage containers, shielding, fume hoods, etc. Attach an explanatory sketch of the facility.

13. Radiation Protection Program

Describe the radiation protection program as appropriate for the material to be used, including: the duties and responsibilities of the Radiation Safety Officer (RSO); control measures; bioassay procedures (if needed); day-to-day general safety instructions to be followed; etc. If the application is for sealed sources also submit leak testing procedures, or if leak testing will be performed using a leak test kit, specify manufacturer and model number of the leak test kit.

14. Waste Disposal

If a commercial waste disposal service is employed, specify the name and address of the company. Otherwise, submit a detailed description of methods which will be used for disposing of radioactive wastes and estimates of the type and amount of activity involved. If the application is for sealed sources and devices and they will be returned to the manufacturer, so state.

15. CERTIFICATION
(This item must be completed by applicant.)

The applicant and any official executing this document on behalf of the applicant named in Item 1.a., certify that this application is prepared in conformity with the Nebraska Department of Health and Human Services Regulation and Licensure Regulations for the Control of Radiation and that all information contained herein, including any supplements attached hereto, is true and correct to the best of our knowledge and belief.

_____
Applicant Name From Item 1.a.

By: _____ *Date:* _____
Signature

_____
Print Name and Title of certifying official authorized to act on behalf of the applicant

APPENDIX B

RESPONSIBILITIES OF THE RADIATION SAFETY OFFICER

The Radiation Safety Officer (RSO) is responsible for implementing the radiation safety program and ensuring that radiation safety activities are performed in accordance with approved procedures and regulatory requirements in the daily operation of the irradiator.

The RSO's duties and responsibilities include:

- Investigating overexposures and implementing corrective actions as necessary;
- Establishing, collecting in one binder or file, and implementing written policy and procedures for:
- Assuring that an irradiator whose construction begins after October 30, 1996, is designed in accordance with the Agency requirements, its construction is monitored, and the features and systems specified in 180 NAC 19-017 are tested and found to be acceptable before loading sources;
- Authorizing the purchase of radiocative material (e.g., new irradiator sources);
- Receiving and opening packages of radioactive material (e.g., casks containing irradiator sources);
- Storing radioactive material;
- Keeping an inventory of radioactive material (e.g., location of each irradiator source (identified by its serial number) within the source rack);
- Using radioactive material safely (e.g., detailed operating procedures);
- Taking emergency action (e.g., detailed emergency procedures);
- Making those changes to operating and emergency procedures that do not need Agency approval (in accordance with the requirements of 180 NAC 19-019);
- Performing inspection and maintenance checks;
- Performing periodic surveys;
- Performing checks and calibrations of radiation detection instruments and water quality devices (e.g., conductivity meters);
- Disposing of radioactive material (e.g., by transfer to authorized recipient);
- Training personnel, including irradiator operators, those permitted unescorted access to the radiation room or the area around the pool of an underwater irradiator, and those who must be prepared to respond to alarms;
- Keeping copies of all records required by Agency regulations, the license and all amendments, and the written policy and procedures required by the regulations and the conditions of the license.
- Establish personnel exposure investigational levels that, when exceeded, will initiate an investigation by the RSO of the cause of the exposure and consideration of actions that might be taken to reduce the probability of recurrence;

- At least annually, review the radiation protection program content and implementation, and then brief management on the results of the review and any needed improvements.

APPENDIX C

INCIDENTS AT LARGE IRRADIATORS

The incidents described here are examples of dangerous or potentially dangerous incidents that have occurred at irradiators. They are described here so that irradiator licensees can learn to avoid the problems that others have had. T he descriptions are taken from NRC Information Notice No. 91-14, Recent Safety-Related Incidents at Large Irradiators," March 5, 1991.

1. Fatality Caused by Source Rack Jam, Bypassed Interlocks. and Fault Survey Meter

At a 340,000 Curie Co-60 irradiator in Israel, a product jam occurred, causing the product transport mechanism to stop, the "source-down" signal to come on, and the gamma alarm to sound. The sounding of the gamma alarm was considered unusual. Acting against operating and safety instructions, the operator did not notify his supervisor and instead handled the situation on his own. He turned the alarm system off by disconnecting the console cables, defeated the door interlock by cycling the power switch, unlocked the door, and entered the radiation room. He did not check the survey meter he carried before entering the radiation room, and consequently he was unaware that the meter was not operational.

Seeing torn cartons, but unable to see that the source rack remained up because it was resting on the edge of a carton, the operator got a cart and began removing the damaged cartons. After about a minute, he began to feel a burning sensation in his eyes and left the room. The operator was not wearing his film badge, but the whole body dose for the 1 ½ to 2 minutes he was in the radiation room was estimated to be about 1,000 to 1,500 rads. The source rack was later released and lowered to the pool under the direction of the supplier, and no further overexposures were reported. The operator died from acute radiation syndrome effects 36 days after the accident.

2. Fatality and Injuries After Sources Fall out of Rack and Interlocks Bypassed

At an 18,000-Curie Co-60 irradiator in El Salvador, the sounding of the source transit alarm alerted the night shift operator (Worker A) that the source was neither fully up nor fully down as a result of a fault condition, which should have caused the source rack to be automatically lowered to the pool. He followed the reset procedure at the control panel, but he had no success in stopping the alarm and releasing the door. He tried to free the source rack by detaching the normal regulated air supply and applying higher pressure to force the source rack into the fully raised position (a procedure not recommended by the supplier). This attempt also failed. The worker was eventually able to stop the alarm, but the general failure light and the "source-up" light remained on. He then manipulated the micro switch system to produce a "source-down" light.

Worker A disabled the 7door interlock system by rapidly cycling the buttons on the radiation monitor panel, while turning the key in the door switch (another procedure not recommended by the supplier), thus simulating the detection of normal background radiation in the radiation room by the fixed monitor and succeeded in opening the door. He then shut off the power supply to the facility and entered the radiation room believing that, as with unpowered x-ray equipment, there would be no continuing radiation. Without first checking the radiation levels with a portable radiation instrument, he began to remove the deformed product boxes that had jammed. At this point he noticed that the descent of the source rack was prevented by the slack cable of the hoist mechanism. Unable to free the rack by himself, he left the radiation room and turned the power back on, noticing that the failure light was "on" and the "source-down" light was intermittent, but that no alarm was sounding.

Worker A then enlisted Workers B and C to help free the source rack. They had no experience or knowledge of the irradiation facility. After assuring Workers B and C that there was no risk as the machine was turned off, the three men entered the radiation room and began removing the jammed product boxes, while standing directly in front of the source rack. As the product boxes were removed and the source rack was lowered to the surface of the water, the workers noticed the blue glow in the pool from Cerenkov radiation. Worker A

was surprised at this and after fully lowering the source rack, he told the others to exit quickly. When leaving the radiation room, Worker A was questioned by Worker B as to the use of the portable radiation monitor that was located some distance from the irradiator. He explained that the instrument was for radiation detection and measurement, but that it had not been necessary to use it.

Worker A became ill minutes after leaving the radiation room and was taken to the hospital. Workers B and C later became ill and also went to the hospital. The company was unaware of the accident for several days because the workers were incorrectly diagnosed as having food poisoning. It was later discovered that some of the source pencils had fallen from the source rack into the pool and that one of the pencils had fallen into the radiation room. At least four more persons were overexposed before the circumstances of the accident were fully realized.

Worker A was hospitalized for extensive radiation burns to his legs and feet and gastrointestinal and hematopoietic radiation syndrome. His right leg was amputated and, 197 days after the accident, Worker A died as a result of his radiation exposure. Worker B was treated for symptoms of acute radiation exposure and severe burns. After the amputation of both legs, he was transferred to a rehabilitation facility 221 days after the accident. Worker C suffered less severe symptoms of radiation exposure and remained on sick leave from work for 199 days after the accident. Long-term effects to these workers may include eye damage from radiation exposure. A more detailed description of the incident can be found in the IAEA publication STI/PUB/847.[1]

3. Faulty Cable Brake Causes Exposed Source, but Good Survey Prevents Overexposure

An irradiator operator noticed that the product had received an unacceptably low dose. He shut down cell operations and, with the source position monitor indicating that the sources were down and the in-cell radiation monitor showing radiation levels at zero, he entered the cell with a portable radiation survey instrument. He noticed elevated radiation levels between 1-2 mR/hr on the survey instrument and aborted his attempt to enter the cell. The operator restricted the area and notified supervisory personnel. Investigation into the cause of the elevated radiation readings revealed that one of the source racks was not fully down and that the top of the rack was about 11/2 feet from the top of the pool. An inspection of the winch mechanism indicated that the cable brake had failed to stop the winch, allowing the cable to completely unwind. As a result, the source rack was raised instead of lowered with the continuing rotation of the winch mechanism. The source rack was then manually lowered into the pool. It was determined that radiation exposure caused deterioration of the wiring in the Geiger-Muller tube of the cell monitor, which caused this system to fail to warn of the elevated radiation levels in the radiation room. The necessary repairs were made to the control panel and the cell monitor, and procedures were instituted to upgrade the safety systems of the facility. The operator followed safety and operating procedures during the incident and avoided overexposure by correctly using the portable survey instrument.

4. Violations Result in NRC Fines

During an inspection and subsequent investigation at an irradiator, NRC identified the following violations: (1) failing to promptly and effectively repair the lock on the personnel-access door to the irradiator cell, (2) modifying a procedure without first obtaining NRC approval (i.e., replacing a safety component in the irradiator start-up system) as required in the license, and (3) deliberately bypassing administrative procedures

[1]STI/PUB/847, "The Radiological Accident in San Salvador," IAEA, Vienna, 1990. Copies can be obtained for reference and training tools from UNIPUB, 4611-F Assembly Drive, Lanham, MD 20706-4391.

and safety interlocks and physical barriers to gain entry to the irradiator cell by climbing over the irradiator cell access door. An NRC investigation also determined that senior licensee management knew of the violations and made incomplete and inaccurate statements to the NRC during an enforcement conference and the subsequent investigations into the circumstances of these violations. The potential for extremely high radiation exposures and the licensee's lack of candor with NRC raised questions about the ability and willingness of the licensee to comply with NRC requirements. NRC considered these violations of the safety requirements to be serious and proposed a civil penalty against the licensee. Senior management involved in this incident are no longer associated with the facility. The licensee has instituted a quality assurance program and additional training requirements.

5. Fines for Deliberate Interlock Bypass

A licensee deliberately bypassed the radiation monitor interlock systems and substituted an administrative procedure for the engineered safeguard provided by the radiation monitor interlock. The substituted cell entry procedure was implemented without NRC review, approval, and incorporation in the license. The alternative procedures did not constitute an entry control device that functioned automatically to prevent inadvertent entry and did not comply with NRC access control requirements. In addition, the licensee installed jumper cables to bypass ventilation system interlocks, which were designed to automatically protect individuals from noxious gases produced as a result of irradiation.

Because of the extremely high radiation exposures that could result if interlocks are not operational, the NRC concluded that this incident was a very serious violation of safety requirements. The licensee was not allowed to operate the irradiator until all safety systems were fully operational. This violation of NRC requirements, along with other safety-related violations, resulted in NRC proposing a substantial civil penalty.

6. Cesium-137 Source Leaks

A leaking cesium-137 source capsule contaminated the pool water at Radiation Sterilizers, Inc.'s plant in Decatur, Georgia, and it remained undetected for an extended period of time because the licensee did not use the pool water monitoring system associated with the demineralizer. The contamination problem was finally discovered when the licensee took discrete samples and performed radiation surveys of the pool water after activation of the radiation level monitoring system, which had automatically locked the sources in the safe-storage position because of the excessive radiation levels while the sources were in the stored position.

Failure to continuously use the demineralizer and pool water monitoring system was contrary to the licensing agency's understanding of the operations. Had the demineralizer been operated continuously, pool water contamination possibly could have been detected earlier, enabling the licensee to begin mitigating the contamination.

7. Crane Brake Fails While Lowering Shipping Cask

A contractor who provided lifting-crane services at a licensed facility was moving a shipping cask from the source storage pool to a mezzanine area, when the cask made an uncontrolled descent of approximately 19 feet. The cask stopped its descent approximately 5 feet below the surface, only after an operator activated a manual brake. No personnel were injured and there was no damage to, or contamination of, the licensee's facility or equipment as a result of this event. However, had the cask not been secured quickly, it could have damaged the radioactive sources in the pool or the pool itself.

This incident was a result of improper brake adjustment of the crane hoist. The crane brake was subsequently repaired and recertified for normal operations in accordance with current Occupational Safety and Health Administration regulations. Braking system inspection and adjustment, as well as functional load testing, are now established daily procedures before crane operation.

8. Faulty Welds Cause Pool Leakage

A licensee experienced a loss of pool water for several weeks that was approximately three times higher than expected from evaporative losses. The licensee performed tests to determine the nature and quantity of the water loss and began daily assays of the pool water to determine compliance with release limits for unrestricted areas. Suspecting a leak in the irradiator pool, the licensee inspected the stainless steel liner and found localized caustic stress corrosion in many welds.

Apparently, welds made during construction of the facility in 1968 were not in accordance with industry standards. Thus, these faulty welds were subject to caustic stress corrosion, which resulted in the recent pool water losses.

9. Hose Rupture Releases Contaminated Water

While the licensee was attempting to decontaminate pool water that had been contaminated by a leaking source, a hose on a filtration system ruptured. Contaminated pool water was then pumped onto the facility floor and leaked outside into the surrounding soil. The licensee failed to report the incident to NRC and made deliberate efforts to prevent NRC's discovery of this incident.

Subsequently, the licensee was indicted by a Federal Court. A conviction resulted in a fine for the company and 2 years probation for a management employee. Licensee failure to make required reports prevents the NRC from performing its radiological health and safety function and from making a timely assessment of the nature and severity of an incident.

10. Licensee Bypassed Access Control Interlocks and Lied to NRC

A licensee deliberately bypassed the safety interlock systems. The NRC subsequently learned that licensee personnel had willfully violated requirements, and that senior licensee management knew, or should have known, of these violations. When NRC attempted to inspect and investigate these suspected violations, senior licensee management knowingly provided false information to the NRC. Subsequent enforcement action included suspension of the license.

11. Line Rupture Causes Loss of Pool Water

A water line fractured in the pool circulation system, which resulted in the loss of 5 feet of pool water. The line break led to a loss of shielding water because the intake and outlet pipes were misaligned during maintenance. T he pipe break appears to have occurred because the pipe was made of polyvinyl chloride, designed for cold water, rather than for the heated water temperatures typical for the irradiator. The piping was replaced with polypropylene Pipe.

12. Frozen Valve Causes Source Rack To Jam in Up Position

A night shift operator noticed that the travel time for the source to reach the fully unshielded position was excessive. After completing the next phase of irradiation, the source would not retract to the fully shielded position, even using emergency equipment. The operator discovered that the solenoid valve, which was supposed to retract the source to a shielded position, was frozen by weather conditions. The frozen valve was in a room above the irradiator facility. The operator went there and turned on a room heater to thaw out the valve so that it would operate. The operator violated license requirements to (1) notify the Radiation Safety Officer (RSO) that the source had not returned to its shielded position because of the frozen valve and (2) obtain RSO permission to enter and heat the room housing the valve.

13. Frayed Cable Causes Source Rack Jam

A licensee had identified a frayed lift cable a few days previously, but instead of immediately replacing the cable, the licensee decided to wait for scheduled maintenance. The cable jammed and froze the source rack in a less than fully shielded position. Employees cut the cables and let the source rack free-fall into the pool. The incident could have been prevented by replacing the frayed cable immediately and selecting cable material with fray resistant qualities.

14. Bent Shroud Prevents Source Rack from Being Lowered

A source rack became stuck in the exposed position. Conveyors stopped, the source-down light came on, but cell radiation levels remained high. Cable-slack data indicated that the rack was stuck about 5-1/2 feet down from its full-up position. The RSO attempted some raising and lowering maneuvers, but the rack then stuck in a full-up position. The RSO, able to run the product containers out of the cell, saw some were misaligned on the carrier. The RSO notified a State inspector, who arrived in the afternoon. It was determined that the rack cable was off its pulley. The bottom of a splice in the cable was resting on the lip of the tube leading to the cell. After the cable was set on its pulley, the cable was guided through the tube and the rack was lowered, but it caught again.

A borrowed radiation-resistant camera arrived the next morning. An adequate view of the rack was obtained by midnight. Apparently the stationary aluminum shroud between product containers and rack had been deflected and caught on the rack frame. The rack was carefully raised and dropped to break the jam. On the second try, the rack broke free and dropped into the pool. Analysis revealed that a product container had probably tipped onto the shroud, causing interference with the rack.

This incident was apparently caused by inadequate design of the shroud. This led to the shroud deforming, which interfered with rack motion. Inadequate maintenance contributed to the problem. The cable should have been replaced instead of spliced. A few months later, the entire source hoist mechanism failed and had to be replaced. This failure occurred when the source rack was submerged.